Complete Summary

GUIDELINE TITLE

Chronic obstructive pulmonary disease.

BIBLIOGRAPHIC SOURCE(S)

Chronic obstructive pulmonary disease. Philadelphia (PA): Intracorp; 2004. Various p.

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Chronic obstructive pulmonary disease, including:

- Emphysema
- Chronic bronchitis

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Pulmonary Medicine

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment and management of chronic obstructive pulmonary disease (COPD) that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with chronic obstructive pulmonary disease

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Physical examination and assessment of signs and symptoms
2. Diagnostic tests:
    - Chest x-ray (CXR)
    - Pulmonary function tests (PFT) (spirometry)
    - Pulse oximetry ("pulse ox")
    - Arterial blood gas sampling (ABG)
    - Sputum culture and sensitivity (C/S) and Gram stain
    - Six-minute exercise test
    - Electrocardiogram (EKG)
    - Absorptiometry; bone mineral density measurements via dual x-ray absorption (DEXA) scanning
    - Sleep apnea study (central or obstructive)
    - Theophylline level

Treatment/Management

1. Medical therapy
    - Bronchodilating medication (ipratropium bromide, beta2 agonists, theophylline)
    - Expectorants and/or mucolytics (acetylcysteine and organic iodide)
    - Aerosol therapy: metered dose inhaler (MDI) and spacer:
        - beta agonists (albuterol [Proventil®, Ventolin®])
        - anticholinergics (ipratropium bromide [Atrovent®])
        - combined albuterol and ipratropium bromide MDI

- Antibiotics or antiviral agents, for acute exacerbations or pneumonia (rimantadine)
- Pneumococcal and influenza vaccines
- Corticosteroids:
    - Oral - prednisone
    - Inhaled - triamcinolone acetonide [Azmacort®], flunisolide [AeroBid®] or fluticasone [Flovent®])
    - Intravenous - methylprednisolone (Solu-Medrol®)
- Supplemental oxygen therapy
- Smoking cessation, (nicotine replacement or oral extended-release bupropion [Zyban®])
- Pulmonary rehabilitation

2. Surgery
    - Lung transplantation
    - Reduction pneumoplasty, lung volume reduction surgery (LVRS)
3. Physical therapy
4. Referral to specialists
5. Case management strategies, including case initiation, case management focus, and discharge

MAJOR OUTCOMES CONSIDERED

- Risks and side effects of treatment
- Treatment efficacy
- Mortality and morbidity of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as -the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Chronic bronchitis
  - Cough, productive of tan or yellow sputum
  - Audible wheezing (asthmatic bronchitis)
  - Slight difficulty breathing, especially with activity (dyspnea on exertion [DOE])
  - Symptom-free periods, or mild symptoms alternating with severe symptoms
- Emphysema
  - Labored breathing with exertion (early)
  - Difficulty breathing at rest (advanced)
  - Fatigue
  - Anxiety
  - Weight loss
  - Possible cough or sputum production

Objective Findings

- Emphysema
  - Dyspnea, at rest or with exertion
  - "Air hunger" (hallmark symptom)
  - Tachypnea and use of accessory respiratory muscles
  - Pursed-lip expirations ("puffing")
  - Decreased breath sounds, hyperresonance, and rhonchi on auscultation
  - Increased anteroposterior thorax diameter, low immobile diaphragm
  - Adequate skin color ("pink puffer")
  - Pulmonary cachexia syndrome--thin, anxious but alert and oriented, in hunched posture
  - Relatively normal blood gases
  - Small, hypodynamic heart
  - Hypotension
- Chronic bronchitis
  - Cough with expectoration (hallmark symptom)
  - Dyspnea (little or no "air hunger," hyperventilation, or anxiety)
  - Relatively normal overall appearance, health, and activity levels
  - Scattered coarse rhonchi, wheezes, and rales
  - Cyanosis ("blue bloater")
  - Pulmonary hypertension
  - Hypoxia and hypercapnia on arterial blood gas sampling (ABG)

- Ventilatory failure and cor pulmonale (see Cor Pulmonale guideline available on the Intra Corp Web site)

Diagnostic Tests

- Chest x-ray (CXR)
  - Establishes diagnosis and identifies acute problems (e.g., infiltrates, atelectasis, congestive heart failure [CHF], pneumothorax, effusions, tumors
  - Emphysema-overinflated lung fields and a small heart
  - Chronic bronchitis-normal lungs and an enlarged heart
  - Annual chest x-ray recommended to monitor disease progression
- Pulmonary function tests (PFT); also called spirometry
  - Measures lung capacities, volumes, flow rates. 2 methods: mechanical (volume displacement); electronic (flow-sensing)
  - Normal values-nomogram (specific for age, height, race, sex). Vital capacity, 3 to 5 L. Forced expiratory volume in 1 second (FEV1), at least 80% of predicted
  - Significant bronchodilator response: FEV1 increases by 200 mL or by 12%
  - Three grades of chronic obstructive pulmonary disease (COPD) airway obstruction as measured by spirometry:
    - Mild: FEV1 50 to 70%; relieved with bronchodilator therapy alone
    - Moderate: FEV1 35 to 49%; symptoms persist despite bronchodilators; evaluate for home O_2 therapy
    - Severe: FEV1 less than 35%; chronic severe symptoms refractory to medicines; evaluate for sleep apnea, alkalosis, hypothyroidism
- Pulse oximetry ("pulse ox")
  - Noninvasive measurement of blood oxygen saturation. Normal, 95% or higher
  - If on O_2 therapy, target range 90–95%
  - Low baseline O_2 saturation common. Degree of change off baseline is often more significant than single values.
- Arterial blood gas sampling (ABG)
  - Stage A: PaO_2 80–100 mm Hg. Normal
  - Stage B: PaO_2 60–80 mm Hg, $PaCO_2$ greater than 45 mm Hg. Home O_2 therapy
  - Stage C: PaO_2 less than 60 mm Hg, $PaCO_2$ less than 35 mm Hg. Modify O_2 therapy
- Sputum culture and sensitivity (C/S) and Gram stain
  - If purulent sputum and symptom exacerbation, begin antibiotic therapy empirically (without sputum C/S or Gram stain results).
  - Obtain sputum C/S to identify specific antibiotics or if tuberculosis, Legionella, fungal or Pneumocystis pneumonia suspected.
- Six-minute exercise test
  - If unable to walk 200 m, begin supplemental O_2 (significant impairment of exercise tolerance).
- Electrocardiogram (EKG)
  - Confirm diagnosis (COPD versus primary heart disease); monitor right heart failure, cor pulmonale, and dysrhythmias.

- Absorptiometry; bone mineral density measurements via dual x-ray absorption (DEXA) scanning
    - Monitors bone loss related to long term steroids; at baseline, at 6 months
    - If two standard deviations below normal, begin exercise and medications.
- Sleep apnea study (central or obstructive)
    - For complaints of nocturnal dyspnea persisting for three months unrelieved by medical management and behavioral adaptations
- Theophylline level
    - Periodic evaluations to prevent drug toxicity in long-term users
    - Target therapeutic range, 5–20 microgram/mL; best clinical value, 12 microgram/mL

Differential Diagnosis

- Non-COPD emphysema (congenital lobar emphysema or alpha-1 antitrypsin deficiency)
- Acute or chronic asthmatic bronchitis
- Restrictive disorders (e.g., interstitial fibroses, silicosis, or sarcoidosis)
- Bronchiectasis with purulent expectorations that obstruct airways
- Infiltrative diseases, such as pneumonia, tuberculosis, or human immunodeficiency virus (HIV) disease
- Cough caused by gastrointestinal reflux (GERD), sinusitis, or post-nasal drip
- Right heart dysfunction
- Subacute left ventricular failure ("cardiac asthma," cough, dyspnea, wheezing, rales)
- Large-airway obstruction caused by tumors or cancer

Treatment Options

Medical therapy

- Medications
    - Bronchodilators
        - Preferred bronchodilator: ipratropium bromide (few side effects)
        - Mild disease: ipratropium bromide and beta2 agonists
        - Moderate: add theophylline (its risks often outweigh benefits)
    - Expectorants and/or mucolytics (e.g., acetylcysteine and organic iodide)
        - Guaifenesin: Humibid® tablet twice daily; Robitussin® liquid six times daily. Monitor hydration status; monitor older patients for toxicity.
    - Aerosol therapy: metered dose inhaler (MDI) and spacer. Teach safe use
        - Mild disease: beta agonist (e.g., albuterol [Proventil®, Ventolin®])
        - Moderate: anticholinergic (e.g., ipratropium bromide [Atrovent®])
        - Often preferred: combined albuterol and ipratropium bromide MDI

- Antibiotics or antiviral agents, for acute exacerbations or pneumonia (See Pneumonia, Community-Acquired guideline available on the Intra Corp Web site)
    - Antiviral agents, e.g., rimantadine (oral, 2–7 days, regardless of vaccination status). Use cautiously if renal or hepatic disease also present.
- Pneumococcal and influenza vaccines
    - Pneumococcal vaccination (intramuscularly [IM]), if no contraindications. Revaccinate if 6 years or more since vaccination and if no contraindications.
    - Influenza virus vaccine (IM), every fall if no contraindications
- Corticosteroids: extended use is controversial, frequently used within 72 hours of acute exacerbation
    - Oral: prednisone tapered over 10–14 days
    - Inhaled: triamcinolone acetonide (Azmacort®) or more potent longer acting flunisolide (AeroBid®) or fluticasone (Flovent®)
    - Intravenous: methylprednisolone (Solu-Medrol®) for 1–2 days, 4 times daily if acute deterioration, often inpatient. Rapid change to oral
    - At initiation, test for tuberculosis (TB) (purified protein derivative [PPD] skin test), diabetes mellitus (DM), hypertension (HTN), cataract
    - At two weeks, obtain follow-up spirometry.
        - If no clear symptom or FEV1 improvement, discontinue steroids.
        - If benefit, taper to lowest effective dosage (e.g., every other day).
- Supplemental oxygen therapy (long term oxygen therapy [LTOT])
    - Nasal cannula (usual), face mask, or reservoir cannula. Maintain PaO_2 at least 60 mm Hg, SaO_2 at least 90%, 18 hours/day
    - Severe disease: Low volume LTOT (e.g., 2 L/min) reduces mortality
        - Titrate O_2 flow, lowest to meet exertional or resting oxygen needs.
        - Noninvasive positive-pressure ventilation: Continuous or bilevel positive airway pressure (CPAP) or (BiPAP) if no mental deterioration
        - Continuous LTOT if PaO_2 55–59 mm Hg or SaO_2 88%; hematocrit (Hct) greater than 55%; congestive heart failure, cor pulmonale, or change in mental status
    - Intubate and mechanical ventilation, for inability to adequately oxygenate via less invasive means and deteriorating respiratory or mental status
- Smoking cessation, cornerstone intervention to improve prognosis
    - At hospitals and volunteer agencies (e.g., American Lung Association)
    - Nicotine replacement or oral extended-release bupropion (Zyban®)
- Pulmonary rehabilitation
    - Patient education, to manage symptoms and improve quality of life

        - Aerobic activity: 45-minute sessions 2–3 times per week for 6 weeks
        - Self-maintenance: continue aerobic program and walk one hour per day
- Surgery
    - Lung transplantation: potentially curative in selected patients (i.e., relatively young nonsmokers)
    - Reduction pneumoplasty, lung volume reduction surgery (LVRS): Clinical indicators
        - Diagnosis of severe emphysema, with computed tomography (CT) scan showing demonstrated bilateral involvement in the upper lobes, AND
        - Nonsmoker for the past 6 months, AND
        - Cardiac ejection fraction of less than 45% with no history of congestive heart failure or myocardial infarction within the past 6 months, AND
        - Pulmonary function test results showing:
            - FEV1 <45% of predicted and if age 70 or older; (FEV1) 15% of predicted or more
            - Post-bronchodilator total lung capacity (TLC) >100% of the predicted value and residual volume (RV) >150% of predicted value; and
            - Resting partial pressure of oxygen (PAO_2) 45 mm Hg or greater; and
            - Resting partial pressure of carbon dioxide ($PACO_2$) <60 mm Hg on room air; and
        - 6-minute walk test greater than 140 meters; AND
        - Patient does not have pulmonary hypertension

Duration of Medical Treatment

- COPD is a chronic, debilitating disease that is likely to require lifelong medical treatment
- Acute exacerbations: most frequently treated on the outpatient basis
- Hospitalization required for worsening dyspnea, signs of respiratory distress: length of stay, 3–4 days. Discharge planning when
    - Parenteral therapy ended or appropriate for less restrictive setting
    - Bronchodilator required no more than every four hours
    - Nonhypoxemic at minimal oxygen requirements
    - Able to safely ambulate in room and engage in activities of daily living

Additional provider information regarding primary care visit schedules, referral options, frequency and duration of specialty care, and physical therapy are provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals for the following scenarios:

- Resolving exacerbation with stabilized dyspnea
- Resolving cough/sputum production
- Resolving weight loss and fatigue
- After hospitalization for respiratory failure with progressive disease

Case Management Directives (refer to the original guideline for detailed recommendations)

Case Initiation

Establish case

- Document baseline information, history, key physical findings, patient's understanding, and safety factors.
- Provide contact information for national support organizations.

Coordinate care

- Advocate for patient by managing utilization and charges.
- Document treatment plan.

Case Management Focus

Activity deficit

- Assess and document specific, reasonable rehabilitation goals using a standardized assessment measure consistently, such as 6-minute test.
- Document plan for coping with, limiting, or preventing mobility deficits due to respiratory insufficiency or failure or venous stasis.

Nutrition deficit

- Encourage high-carbohydrate foods in small frequent quantities (e.g., 6 times daily).
- Promote adequate hydration: underhydration may lead to hemoconcentration (thicker excretions, slowed blood flow) or hypervolemia (may exacerbate swelling).

Pain control

- Evaluate pain associated with chronic or paroxysmal cough, pleurisy, or rib fractures; document interventions to manage or alleviate pain.

Physiologic complications

- Direct the patient to immediately report to attending physician or activate emergency medical treatment (EMT) system as appropriate (see original guideline for additional detail).
- Assess and document teaching and safety measures including appropriate medication administration. Proper use of inhalers and MDI.

Respiratory instability

- Document stage 0-4 respiratory deficits (see the "Description" section of the original guideline) and interventions taken.

- Monitor for drug-induced bronchospasm (due to alcohol, aspirin, cholinergics, opiates, propranolol, prostaglandin-1 inhibitions, reserpine, or sedatives). Change or adapt medication therapy.
- Monitor compensatory tachypnea in ongoing O_2 therapy. (Presence indicates intact CO_2-respiratory drive chemoreceptors; absence indicates increased risk of apnea.)
- Assess and document teaching regarding breathing pattern efficiency—rapid shallow respirations (smaller tidal volumes and shortened inspiratory times).

Skin integrity deficit

- Assess and document interventions regarding deficits caused by bedridden status, bladder control problems, inadequate nutrition-hydration, pressure insensitivity.

Discharge

Discharge from Case Management (CM)

- Verify return to independence or optimally stabilized functional status in closing conversations with patient, caregiver, physician(s), and providers.
- Instruct and reassure regarding reestablishment of CM case if needed

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Not stated

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment, and management of chronic obstructive pulmonary disease (COPD) that assists medical management leaders in making appropriate benefit coverage determinations

POTENTIAL HARMS

None stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Chronic obstructive pulmonary disease. Philadelphia (PA): Intracorp; 2004. Various p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2004 Jul)

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

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AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

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